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No. 91-13

IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

GENETICS INSTITUTE, INC., and
CHUGAI PHARMACEUTICAL CO., INC.,
Petitioners,

v.

AMGEN, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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RESPONDENT'S BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the court of appeals erred in its fact-bound determination that U.S. Patent No. 4,703,008 satisfied the requirements of 35 U.S.C. § 112 based on the district court's factual findings that the patent's written specification properly disclosed the best mode of the invention known to the inventor and was sufficient to enable a person skilled in the genetic engineering art to carry out the best mode of the invention without undue experimentation.

2. Whether the court of appeals erred in its determination that, as a matter of law, respondent had met its burden of showing that U.S. Patent No. 4,677,195 had not satisfied the "enable[ment]" requirement of 35 U.S.C. § 112 because all efforts of the petitioners and others to practice the claimed invention according to the teachings of the patent had failed to achieve the *in vivo* specific activity limitation claimed by the patent.

RULE 29.1 DISCLOSURE

Amgen, Inc. does not have a parent company. Its only non-wholly owned subsidiaries are Kirin-Amgen, Inc. and Amgen Clinical Partners, L.P.

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RESPONDENT'S BRIEF IN OPPOSITION

Respondent Amgen, Inc. ("Amgen") hereby opposes the petition for a writ of certiorari filed by Genetics Institute, Inc. ("GI") and Chugai Pharmaceutical Co., Inc. ("Chugai") in this case.

STATEMENT

This case involves nothing more than a routine, fact-bound patent dispute, involving two patents, with different issues as to each patent. Not only is there no conflict among the courts of appeals, there is not even a legal issue, given the factual findings on which the two lower courts have agreed. Accordingly, there is nothing further to be done, and certainly nothing worthy of this Court's attention.

Because petitioners make such extravagant claims about the questions presented by the holdings of the court of appeals—questions that are not presented by anything in that court's opinion—a somewhat lengthier than usual description of the proceedings below is appropriate. These proceedings show that a written disclosure is the generally accepted method of satisfying 35 U.S.C. § 112, and that the court of appeals correctly approved the specific disclosure in this case as satisfying the language and purpose of the statute. Thus, the premises of the petition are false: with respect to Amgen's patent, the court of appeals did not hold categorically that deposit of genetic material is never required and the court did not create new law in finding that the written disclosure here complied with the statute. Similarly, with respect to the issue of lack of enablement of GI's patent, the court made clear that it was neither shifting the burden of proof nor substituting its own findings for those of the district court.

A. *The '008 Patent*

1. It is undisputed that Dr. Lin of Amgen was "the first to clone the [EPO] gene." Pet. App. 39; *see* Pet. at 7. Dr. Lin thus achieved "a long sought and difficult scientific goal." Pet. App. 12, 16. The isolation of the human EPO gene made it possible to genetically engineer cells to make recombiant EPO ("rEPO"). It is also undisputed that Dr. Lin's discovery has had great therapeutic benefits. By stimulating production of red blood cell levels, "[a]dministration of EPO provides life-saving or life-enhancing treatment for those suffering from anemia, kidney failure, and other disorders." Pet. at 2, 4; *see* Pet. App. 3, 7. Recombinant EPO is considered the greatest advance for the treatment of kidney dialysis patients in 25 years.

The best mode of the invention contemplated by Dr. Lin was fully disclosed in Example 10 of the patent application for U.S. Patent No. 4,703,008 (" '008"). Spe-

cifically, Example 10 sets forth the steps for transfecting mammalian cells with plasmids containing DNA for rEPO. Pet. App. 127. In particular, Example 10 discloses in detail that Dr. Lin used a specific publically available strain of chinese hamster ovary ("CHO") cells as starting materials. *Id.* at 16. It is undisputed that these starting materials are common and publicly available. *Id.* at 20, 127. Example 10 also showed the ongoing process of how to isolate genetically-homogeneous clones with the highest EPO production rate using a limited dilution cloning procedure that was well known in the art. *Id.* at 20, 127, 131. Even petitioners' experts conceded that these procedures were "standard." *Id.* at 20.

The disclosure set forth in the '008 specification enables others in the field without undue experimentation to reproduce transfected CHO strains with equivalent levels of EPO production. Pet. App. 20, 22. Petitioners' own experts have conceded this. *Id.* at 127-28. Indeed, GI concluded that "Amgen's first cloning of EPO is certainly patentable." C.A. App. 20,853A.

2. The petition attempts to convey the impression that the court of appeals somehow reversed the district court on the '008 patent. To the contrary, the district court, through the magistrate, determined that the written disclosures set forth in '008's specification satisfied all the pertinent disclosure requirements of patent law. Pet. App. 121-32. With respect to the requirement of 35 U.S.C. § 112 that Amgen's application "set forth the best mode contemplated by the inventor of carrying out his invention," the court correctly noted that GI and Chugai bore the burden of showing by clear and convincing evidence that the '008 specification was inadequate to disclose Dr. Lin's best mode for his invention. *Id.* at 126. In response to the argument that Amgen was required to deposit transfected CHO cells, the district court found that Example 10 set forth not only the DNA sequences

and vectors and the production rates of the best mode CHO cell strains, but also the procedures for transfecting CHO cells, gene amplification, and the ongoing process of limited dilution cloning to isolate the genetically-homogeneous clones with the highest EPO production capacity. *Id.* at 127-28. The district court found, based in part on petitioners' own concessions, that these procedures were standard. *Id.* at 127. The district court further found that the '008 specification enabled one of ordinary skill in the art to produce CHO host cell strains with equivalent levels of EPO production to those in Example 10 of the '008 patent. *Id.* at 131-32. In particular, the court found that Amgen had no information at the time of the filing of the '008 application which would have revealed any "characteristics" pertinent to EPO production that the written disclosure did not reveal. *Id.* at 132. Accordingly, the district court "decline[d] *in the circumstances of this case* to hold that the only way to meet the best mode requirement for a transfected host cell is to deposit." *Id.* (emphasis added).

3. The court of appeals affirmed the district court's findings that '008's disclosure of the best mode was adequate. The Federal Circuit agreed with the district court that settled law established that the test was whether the written disclosure was "adequate." Pet. App. 18, 21, 22-23. The court expressly recognized that if, but only if, disclosure is adequate, then the inventor has satisfied "the *quid pro quo* of the patent grant." *Id.* at 18. The Federal Circuit further noted that under settled law satisfaction of this best mode requirement is a question of fact. *Id.* at 17. In particular, prior case law involving natural organisms established that when the written description allowed preparation of the invention from known materials without undue experimentation based on the procedures described in the patent specification, a deposit was unnecessary. *See id.* at 19, 21 (citing authorities).

The court of appeals therefore affirmed as not "clearly erroneous" the district court's finding that the petitioners

had not met their burden of proving that the best mode had been inadequately disclosed by the '008 specification. *Id.* at 17, 18. In so holding, the court of appeals relied on the district court's specific findings that (1) the starting materials were known and publicly available, (2) the starting materials were described, (3) the ongoing procedures for isolating the best cell strains described were standard and did not require undue experimentation, and (4) the patent specification enables others to produce transfected CHO cell strains with equivalent levels of EPO production. *Id.* at 17, 18, 20, 22. The court of appeals emphasized that its affirmance of the district court's factual findings was limited to the facts of this case:

> If the cells can be prepared without undue experimentation from known materials, based on the description in the patent specification, a deposit is not required. . . . *Since the court found that that is the case here*, we therefore hold that there is no failure to comply with the best mode requirement for lack of a deposit of the CHO cells, when the *best mode* of preparing the cells has been disclosed and the best mode cells have been enabled, *i.e.*, they can be prepared by one skilled in the art from known materials using the description in the specification. *Id.* at 21 (initial emphasis added).[1]

B. *The '195 Patent*

1. In stark contrast to Amgen's scientific success and enabling patent disclosures, GI failed in U.S. Patent No. 4,677,195 ("'195") to create any invention with respect to EPO. In its '195 application, GI claimed that it had created a homogenous EPO product derived from human urine having an *in vivo* specific activity of at least

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[1] Although petitioners sought rehearing and rehearing en banc concerning the '195 patent, they did not seek rehearing or en banc review concerning the '008 patent.

160,000 IU/AU.[2] Pet. App. 31, 40. GI attempted to bootstrap its hypothesis concerning the potency of homogenous EPO into claims sufficiently broad as to block Amgen's pioneer work in providing therapeutically useful rEPO to the public. The facts, however, contradicted GI's claim and showed that the '195 patent was a paper patent that did not enable the claimed invention.

It is undisputed that GI never produced EPO with the *in vivo* specific activity level claimed in the '195 patent using the teachings of the '195 patent. *Id.* at 32-33. GI's effort in Example 2 of the '195 patent to obtain purified rEPO, the only form of EPO with therapeutic value, failed completely. *Id.* at 34, 92, 186; *see also* C.A. App. 8480-81, 34,229 (uEPO has no known therapeutic value). GI did not even produce any uEPO having an *in vivo* specific activity level of 160,000 IU/AU using the techniques described in the '195 patent. *See id.* at 173, 175. Others who employed the techniques of the '195 patent could only produce uEPO with an activity level of 101,000 IU/AU, *id.* at 33, well below the purity of uEPO—128,000 IU/AU—achieved in the prior art. C.A. App. 9602-03, 19,214, 22,187, 22,253. Finally and most telling, GI and Chugai reported to the FDA that their uEPO purified "to homogeneity" in fact had a specific activity level of only 109,000 IU/AU, again well below that previously described in the prior art. Pet. App. 32; C.A. App. 18,896, 22,181.

2. The district court was "troubl[ed]" by evidence that the '195 specification failed to enable the claims of the '195 patent. *Id.* at 186. In particular, the district court found that in Example 2 of the '195 patent "[i]t is undisputed that GI tried and failed to purify rEPO using RP-HPLC," the procedure reported in the patent, obtaining instead only 62% purity. *Id.* at 186; *see also id.* at 92. Further, the court found that GI had never actually

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[2] Specific activity relates to the potency of EPO in stimulating formation of red blood cells when administered to animals. Pet. App. 31 n.10.

produced any homogenous uEPO having the claimed *in vivo* activity pursuant to the procedures described in the '195 patent and having the claimed specific activity. *See id.* at 173, 175. Nonetheless, the court held that the '195 patent was enabled based on an *in vitro* test result of uEPO by Kung showing a specific activity of 173,640 IU/AU. *Id.* at 186. The district court did not address the inconsistency between this holding and its own earlier holding that for purposes of construing '195's claims an *in vivo* measure had to be used. *Id.* at 164. This prior holding was based on the court's findings that there was a "material difference" between *in vitro* and *in vivo* testing and that "all the experts testified that an *in vivo* activity measurement was ultimately required to determine the specific activity." *Id.* Thus, although the district court construed the claims of the '195 patent as requiring *in vivo* specific activity, the district court relied on Kung's *in vitro* specific activity measurement in concluding that the claims of the '195 patent were enabled.

3. With respect to the '195 patent, the court of appeals accepted the district court's construction of the claims as requiring *in vivo* activity, but upon review of the district court's findings held that the *in vivo* specific activity limitation had not been enabled. The court noted that it was settled that enablement is a question of law. Pet. App. 32 (citing authority). The court expressly held that "the burden of showing non-enablement is Amgen's, not GI's." *Id.* at 34. In holding that Amgen had met this burden as a matter of law, the court of appeals relied on a number of uncontroverted facts and subsidiary findings by the district court: (1) The district court found that the '195 claims required an *in vivo* specific activity measurement for claims construction purposes and thus should have used this measure for enablement purposes. *Id.* at 32. The district court therefore committed legal error in relying on Kung's *in vitro* test "despite the demonstrated disparity between the results of

in vitro and *in vivo* testing." *Id.* at 33. (2) Petitioners had never prepared EPO with a specific activity of at least 160,000 IU/AU *in vivo* using the disclosed methods. *Id.* at 32. Although GI had made an estimate that homogeneous EPO had such a theoretical specific activity, GI did not have "a workable method for actually obtaining the pure material that it claimed." *Id.* at 32-33. (3) To the contrary, "the district court found that the only purification attempt on rEPO in the manner set out in the '195 patent failed to provide homogeneous EPO." *Id.* at 34. (4) The "district court found that GI reported to the FDA that the specific activity of uEPO, based on *in vivo* bioassays, was only 109,000 IU/AU." *Id.*

Based on these findings, the court below concluded that as a matter of law Amgen had met its burden of showing non-enablement. Again, the court narrowly limited its ruling to the facts of this case:

> [I]n the case of a challenged patent, when substantial discovery has occurred, and there is no credible evidence that the claimed purified material can be made by those skilled in the art by the disclosed process, and all evidence from both the inventor and his assignee and from third parties is to the contrary, we conclude that Amgen has met its burden to show that the claims have not been adequately enabled. We do not hold that one must always prove that a disclosed process operates effectively to produce a claimed product. But, under these circumstances, we conclude that the court erred in holding that claims 1 and 3 were properly enabled. Pet. App. 34.

REASONS FOR DENYING THE PETITION

1. The question presented concerning the '008 patent raises no issue of general significance and the holding below on that issue conflicts with no decision of this Court or any other court. Rather, this question involves only the fact-bound and mundane application to very specific facts

of established interpretations of a narrow, technical issue of patent law under 35 U.S.C. § 112. This Court has particular reason to defer on such an issue to the special expertise of the Federal Circuit, a court created by Congress " 'to provide nationwide uniformity in patent law.' " *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989) (quoting H.R. Rep. No. 312, 97th Cong., 1st Sess. 20 (1981)); *see also* S. Rep. No. 275, 97th Cong., 1st Sess. 3-6 (1981) (Federal Circuit created to provide "definitive" answers to patent questions so as to relieve burden of this Court).

a. The fundamental and repeated premise of petitioners' argument—and the sole basis for their extravagant rhetoric concerning separation of powers, trade secrets, and the like—is that prior to the decision below, courts interpreted Section 112 as *always* requiring a deposit of natural organisms. *See* Pet. at 2, 16, 21. This premise, however, is flatly incorrect and therefore can provide no basis for granting the petition. Stated bluntly, even the cases relied on by petitioners expressly state that a deposit of a natural organism is not necessary when one "skilled in the art . . . can reproduce the invention from the written disclosure." *In re Argoudelis*, 434 F.2d 1390, 1393 (C.C.P.A. 1970); *see also id.* at 1392 ("ordinarily" deposit is not required); *Feldman* v. *Aunstrup*, 517 F.2d 1351, 1354-55 (C.C.P.A. 1975), *cert. denied*, 424 U.S. 912 (1976); *In re Lundak*, 773 F.2d 1216, 1218 (Fed. Cir. 1985); *Ex Parte Kropp*, 143 U.S.P.Q. 148, 153 (Pat. Off. Bd. App. 1959).[3]

The best mode ruling below is not only consistent with prior cases, it is well supported by the language of the statute. There is simply no support for requiring a deposit when, as here, the written specification has been

[3] Even if there were any conflict with the cases cited by petitioners—and there is not—it would be at most an intracircuit conflict, and thus not worthy of this Court's review. *See Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957); *see also supra*, at 5 n.1.

found by two courts to have adequately disclosed the best mode of the invention and to have allowed that best mode to be readily reproduced. Section 112 states, in pertinent part, that:

> The specification shall contain a *written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and *shall set forth the best mode contemplated by the inventor of carrying out his invention* (emphasis added).

There is no deposit requirement expressed anywhere in this statute. Rather, this language plainly envisions a written form of disclosure. Thus, written descriptions and drawings traditionally constitute the disclosure of the invention. *See In re Gay*, 309 F.2d 769, 774 (C.C.P.A. 1962).

Thus, depositing biological materials is an exception to the norm of written disclosure and is, therefore, applicable only when, unlike here, written disclosure does not permit reproduction of the invention without undue experimentation. *See Argoudelis*, 434 F.2d at 1392-94; *see also* Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J. Pat. Off. Soc'y 569, 579 (1985) ("the deposit requirement evolved as a nonstatutory remedy to the problem of a nonenabling written disclosure").[4] The courts have uniformly rejected elevating this alternative means of statutory compliance into a mandatory statutory requirement in every case when, as here, the written disclosure has been found to be adequate. *See, e.g., Feldman*, 517 F.2d at 1355 (deposit is not "mandatory for a sufficient specification"). Instead, the courts have consistently addressed

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[4] The petition does not challenge the holdings of the two courts below that the '008 specification fully satisfied the "enable[ment]" requirement of § 112.

whether a deposit is required to satisfy the requirements of 35 U.S.C. § 112 as a question of fact to be resolved on a case-by-case basis. *See* Pet. App. 17; *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988); *Feldman*, 517 F.2d at 1355 (the requirement of a deposit should not be "elevat[ed beyond] the specific facts presented in *Argoudelis* to the status of a rule of law"); *see also DeGeorge* v. *Bernier*, 768 F.2d 1318, 1324 (Fed. Cir. 1985) ("best mode [determination] is a question of fact").

Accordingly, contrary to the fundamental premise of the petition that the ruling below not requiring a deposit in this case is unprecedented, courts had long held that Section 112 did not require a deposit of a natural organism when the facts revealed that the written disclosure was adequate. *See Tabuchi* v. *Nubel*, 559 F.2d 1183, 1187 (C.C.P.A. 1977) (starting materials were available and screening process was straightforward); *Merck & Co.* v. *Chase Chem. Co.*, 273 F. Supp. 68, 76 (D.N.J. 1967); *see also* 37 C.F.R. § 1.802(b) (1990) ("Biological material need not be deposited, inter alia, if it is known and readily available to the public or can be made or isolated without undue experimentation."); 52 Fed. Reg. 34,080, 34,081, 34,088 (1987). Similarly, at least four cases prior to the decision below had rejected arguments that biotechnology material needed to be deposited in order to satisfy Section 112. *See, e.g., In re Wands*, 858 F.2d at 736-37 (no need to deposit hybrid cells using monoclonal antibodies); *Hybritech, Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384-85 (Fed. Cir. 1986) (enablement and best mode requirements for cells producing monoclonal antibodies satisfied by written description), *cert. denied*, 480 U.S. 947 (1987); *Hybritech, Inc.* v. *Abbott Laboratories*, 4 U.S.P.Q.2d 1001, 1011-12 (C.D. Cal. 1987) (Kosinski, J., sitting by designation) (same), *aff'd*, 849 F.2d 1446, 1453 (Fed. Cir. 1988); *Ex parte Goeddel*, 5 U.S.P.Q.2d 1449, 1450 (PTO Bd. of App. & Interferences 1987) (deposit of genetically-engineered interferon not required). Thus, prior to the decision

below, "[i]t [was] well-settled . . . th[at] biological materials need not be deposited when the invention can be practiced without undue experimentation from biological materials available in prior art" and this established factual test had been applied to both natural and genetically-engineered organisms. *Abbott Laboratories*, 4 U.S.P.Q.2d at 1011.[5]

Nor can petitioners make this case appear novel or unprecedented by contending that the court of appeals confused the "enable[ment]" and "best mode" provisions of Section 112. *See* Pet. at 22-23. There is simply no basis for reading the "best mode" requirement of Section 112 to require deposit when, as here, the "best mode" of the invention is adequately "set forth" by the written description. First, all of the deposit cases relied on by petitioners only address the "enable[ment]" requirement of Section 112. *See, e.g., Argoudelis*, 434 F.2d at 1392-94. Those cases establish a case-by-case test concerning whether a deposit is required and would be rendered a nullity under petitioners' *per se* approach. Second, the exact same case-by-case test applied by the court of appeals had previously been applied in holding that written specifications, without deposit of the organism, satisfied *both* the "best mode" and "enable[ment]" requirements of Section 112. *See Monoclonal Antibodies*, 802 F.2d at 1384-85; *Abbott Laboratories*, 4 U.S.P.Q.2d at 1011-12,

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[5] The scholarly literature has also long concluded that the precision of recombinant DNA technology would under certain circumstances permit written disclosure to satisfy the requirements of Section 112 without a deposit. *See, e.g.*, Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J. Pat. Off. Soc'y, 569, 581 (1985); Meyer, *Problems and Issues in Depositing Microorganisms for Patent Purposes*, 65 J. Pat. Off. Soc'y 455, 459-60 (1983); I. Cooper, *Biotechnology and the Law*, § 5.05[2][e] at 5-66 to 5-67 (1991) (citing 1981 articles). Moreover, the literature demonstrates that requiring a deposit when, as here, written disclosure has been found to be adequate could only have adverse policy effects. *See* Greenlee, *Biotechnology Patent Law: Perspective Of The First Seventeen Years, Prospective On The Next Seventeen Years*, 68 Denv. U. L. Rev. 127, 134 (1991); Hampar, *supra*, at 590.

aff'd, 849 F.2d at 1453; *see also* 37 C.F.R. § 1.802(b) (1990) (regulation addressing all requirements under Section 112); Manual of Patent Examining Procedure ¶ 608.01(h) (best mode provision does not require "disclosure of a specific example"); *cf. Merck & Co.*, 273 F. Supp. at 76 (addressing issue as sufficiency of disclosure). Third, both lower courts explained the relationship between the two statutory requirements and that here the written description and publicly available starting materials readily enabled reproduction of not just any mode of the invention but rather the *best mode* of the invention, thus demonstrating that such best mode had been adequately disclosed. *See* Pet. App. 17-23, 121-32.[6]

The ruling below in this case therefore merely applied the established test derived from prior cases for when a deposit is required to the specific facts of this case as found by the district court. Contrary to the protestations of petitioners (*see* Pet. at 10, 13, 17, 19), nothing in the decision below held or even suggested that genetically-engineered organisms never need to be deposited. *See* Pet. App. at 21 ("the [district] court found that [it] is the case here" that the test set forth by prior cases for adequate written disclosure had been satisfied); *see also id.* at 17-22; *supra*, at 4-5. Commentators have already recognized that the best mode ruling in this decision did not make any new law. *See* Baechtold, Perry, Tegfelt,

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[6] As the context makes clear, the statement of the court of appeals that "[t]his presents us with a question of first impression" refers to GI's and Chugai's express contention that deposit of cells involved in genetically-engineered inventions should always be required regardless of the adequacy of the written disclosure. Pet. App. 19. Plainly, the Federal Circuit had itself previously twice used the established case-by-case approach in holding that the best mode requirement as well as the enablement requirement had been satisfied by written disclosure without the deposit of cells producing genetically-engineered microorganisms. *See Hybritech* v. *Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384-85 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); *Hybritech, Inc.* v. *Abbott Laboratories*, 849 F.2d 1446, 1453 (Fed. Cir. 1988), *aff'g*, 4 U.S.P.Q.2d 1001, 1011-12 (C.D. Cal. 1987).

Knudsen & Carson, *Property Rights in Living Matter: Is New Law Required?*, 68 Denv. U. L. Rev. 141, 169 (1991) (*Amgen* "referred to established principles and declined to create a new 'best mode' requirement for biotechnological inventions").[7]

Because the best mode ruling below merely applied a settled interpretation of Section 112 to particular facts, this ruling has no significance for patent applications beyond the one at issue in this case.[8] Simply put, there is no reason for this Court to review the fact-bound determination by the courts below that the written disclosure was adequate in this case. It is well-established that this Court does not "grant a certiorari to review evidence and discuss specific facts," *United States* v. *Johnston*, 268 U.S. 220, 227 (1925), much less findings of fact "in which two courts below have concurred." *United States* v. *Doe*, 465 U.S. 605, 614 (1984).[9] Nothing more is at issue in this case.

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[7] Indeed, the article cited in the petition (Pet. at 12) for the proposition that the decision below holds that genetically-engineered organisms never need to be deposited states precisely the opposite. In a portion omitted by petitioners from their quotation, the article states that a "never deposit" interpretation is *contrary* to what the Federal Circuit held in this case and another recent deposit decision, *Scripps Clinic & Research Found.* v. *Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). *See* Halluin & Wegner, *Amgen* and *Scripps:* The New Biotechnology Practice, 10 Biotechnology Law Rep. 191, 208 (1991) (reprinting article cited by petition). In fact, the erroneous interpretation referred to by the article is attributed to counsel for the losing litigant in *Scripps*. *See id.* at 208 nn.58-59.

[8] Moreover, a regulation recently promulgated by the Patent and Trademark Office rejects a deposit requirement when, as here, written disclosure is adequate. *See* 37 C.F.R. § 1.802(b) (1990) ("Biological material need not be deposited, inter alia, if it is known and readily available to the public or can be made or isolated without undue experimentation."). That regulation, which was not promulgated until after the patent applications in this case, will govern future patent applications.

[9] *See also NLRB* v. *Hendricks County Rural Elec. Membership Corp.*, 454 U.S. 170, 176 n.8 (1981) (dismissing writ as improvi-

b. Despite the petitioners' rhetoric, the ruling below is fully consistent with the mandate of Congress, the traditional function of courts, and this Court's decision in *Diamond* v. *Chakrabarty*, 447 U.S. 303 (1980). The rule that deposit is *sometimes* required by Section 112 is not mandated by the language of the statute itself. *See supra*, at 9-10. Rather, courts construing Section 112 have required deposit only when necessary to fulfill the statutory requirement of "enable[ment]." *See supra*, at 9-10, 11-

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dently granted because case presented "primarily . . . a question of fact"). Because '008's written specification disclosed all that patent law required, the petition's contention that Amgen nonetheless committed concealment (*see* Pet. at 23-25) is frivolous. First, both general and patent law principles require a duty to disclose as a necessary element of concealment. *See, e.g., Chiarella* v. *United States*, 445 U.S. 222, 229-30, 232 (1980); *Charles Pfizer & Co.* v. *FTC*, 401 F.2d 574, 583 (6th Cir. 1968), *cert. denied*, 394 U.S. 920 (1969). Because '008's written disclosure here was adequate, no duty to deposit the transfected CHO cells could arise and thus there could be no concealment. *See* Pet. App. 23 (stating that because the written specification adequately disclosed the best mode, there was no concealment and therefore the nondeposit of transfected CHO cells was "irrelevant"). Second, contrary to the petition at 11, although the district court stated there was some "evidence of concealment," it expressly determined that this evidence was "not enough" for GI to meet its burden of showing concealment. *Id.* at 131. Specifically, (1) Amgen's deposit of certain cells but not the CHO cells was not concealment. Each of the deposits was made for the purpose of providing access to potentially *unique* starting materials. In contrast, the CHO starting materials were publicly available. *See* Pet. App. 20, 127. (2) As the district court found, neither the examiner nor those skilled in the art were misled because the written specification did disclose the best mode use of CHO cells and it was already well recognized by those skilled in the art that E. Coli and yeast cells could not be the best mode. *Id.* at 129, 130, 131-32. (3) As the district court found, the examiner did not order deposit of the transfected CHO cells. *Id.* at 132. Rather, the examiner accepted Amgen's written and oral arguments that such a deposit was not necessary and issued the patent accordingly. *See id.* at 21, 131-32. Petitioners' reference to 35 U.S.C. § 114 (*see* Pet. at 19) is entirely misplaced. This section of the patent code provides for the patent office examiner to request models or specimens to show that inventions (such as a perpetual motion machine) are operable.

12. The two courts below found no such necessity here. This process of construing the general terminology of a statute and applying it to specific facts to effectuate the statute's purpose is a traditional function of courts and was specifically approved in this context in *Diamond*. See 447 U.S. at 315.

Nor is the ruling below in any way inconsistent with the holding of *Diamond* that the patent laws apply to genetically-engineered life forms. First, this Court expressly left open all questions of how the various requirements of patent law would apply to genetically-engineered organisms. *See* 447 U.S. at 307 & n.5. *Diamond* in no way required that all rules applicable to natural organisms should apply in exactly the same fashion to genetically-engineered organisms without regard to how differences between the two kinds of organisms relate to fulfillment of the statutory purposes. *Cf. Fortnightly Corp.* v. *United Artists Television, Inc.*, 392 U.S. 390, 396 (1968) ("We must read the statutory language of 60 years ago in light of drastic technological change."). Second, in any event, the Federal Circuit dealt with the deposit issue in this case exactly as it does in natural organisms cases, *i.e.*, by applying the case-by-case rule developed in those cases to the specific facts of this case rather than creating a new rule applicable to all cases regardless of the facts. *See supra*, at 8-12.

c. In any event, this Court should not grant certiorari to review an issue that is of no importance even to the particular case before the Court. *See Monrosa* v. *Carbon Black Export, Inc.*, 359 U.S. 180, 184 (1959). The Federal Circuit alternatively held that claim No. 2 of Amgen's patent, which covers the isolated DNA sequence, was valid without regard to the validity of the host cell claim Nos. 4, 6, 23-27, and 29. *See* Pet. App. 17 n.5. The petition concedes that unless this alternative holding is reversed, the principal question presented is of no significance to this case "since it is impossible for anyone to create transfected host cells without using and reproducing the

isolated DNA sequence on which Amgen would retain a patent monopoly." Pet. at 26. This alternative holding, however, is plainly correct because the host cells are entirely unrelated to the DNA sequence and a best mode violation would only invalidate the specific claims involved. *See Northern Telecom, Inc.* v. *Datapoint Corp.*, 908 F.2d 931, 940 (Fed. Cir.) (only specific claims invalidated), *cert. denied*, 111 S. Ct. 296 (1990).[10] Both courts below found that the isolated and purified DNA sequence, by itself, was an invention. Pet. App. 11, 95. That DNA sequence could not have been any more fully disclosed and it was deposited. *See id.* at 70, 127. In any event, the exact relation between the host cell claims and the DNA sequence claim is a question of no significance beyond the facts of this case and thus not worthy of this Court's review.

2. The question presented concerning the '195 patent is entirely fact-bound and plainly not worthy of this Court's review. Indeed, the petition itself appears to recognize that this second question standing alone is not worthy of certiorari. *See* Pet. at 29.

a. The contention that the burden of proof was placed on GI and Chugai in contravention of 35 U.S.C. § 282 (*see* Pet. at 27) is frivolous. The decision below ex-

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[10] Petitioners attempt an end-run around this basic principle of patent law by attempting to redefine the invention involved here as "producing EPO by recombinant DNA technology." Pet. 26. Petitioners misperceive the goal of an invention as opposed to the definition of an invention. The "invention" of every patent is defined strictly by the claims of the patent. *Aro Mfg. Co.* v. *Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961); *Continental Paper Bag Co.* v. *Eastern Paper Bag Co.*, 210 U.S. 405, 419-20 (1908); *Environmental Designs Ltd.* v. *Union Oil Co.*, 713 F.2d 693, 699 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984). Here, the isolated DNA sequence and the vectors are separate aspects of the present invention and are defined by separate patent claims. See Pet. App. 11, 95. Nothing in the cases cited by petitioners, *see* Pet. at 25 n.15, suggests that unrelated claims would be invalidated by a best mode violation.

plicitly states twice that "[t]he burden of showing nonenablement is Amgen's, not GI's." Pet. App. 34; *see also id.* ("Amgen has met its burden to show that the claims have not been adequately enabled").[11]

b. The contention that the court of appeals substituted its own fact findings is equally unworthy of this Court's review. The petition does not challenge the well-settled rule that enablement is a question of law. *See* Pet. App. 32; *see, e.g., Moleculon Research Corp.* v. *CBS, Inc.*, 793 F.2d 1261, 1268 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987). Accordingly, it was entirely appropriate for the court of appeals to determine the legal issue of enablement. It was also entirely proper for the court of appeals to make this determination based on the facts as found by the district court or revealed as uncontroverted by the record. *See* Pet. App. 32-34; *supra*, at 5-7; *see also Boyle* v. *United Technologies Corp.*, 487 U.S. 500, 513-14 (1988) (where judgment as matter of law is appropriate, there should not be remand to trial court). Numerous decisions of the Federal Circuit reveal that it correctly understands and properly applies Fed. R. Civ. P. 52(a). *See, e.g., Smithkline Diagnostics, Inc.* v. *Helena Laboratories Corp.*, 926 F.2d 1161, 1164 (Fed. Cir. 1991); *Midwest Plastic Fabrications, Inc.* v. *Underwriters Laboratories, Inc.*, 906 F.2d 1568, 1572 (Fed. Cir. 1990); *Pennwalt Corp.* v. *Durand-Wayland, Inc.*, 833 F.2d 931, 936 (Fed. Cir. 1987) (Rule 52(a) does not permit "*de novo*" fact finding by court of appeals), *cert. denied*, 485 U.S. 961 (1988); *Panduit Corp.* v. *Dennison Mfg. Co.*, 810 F.2d 1561, 1568-69

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[11] Moreover, when the challenger has produced evidence sufficient to make a "*prima facie* case of invalidity. . . . the party relying on validity is then obligated to come forward with evidence to the contrary." *Ralston Purina Co.* v. *Far-Mar-Co, Inc.*, 772 F.2d 1570, 1573 (Fed. Cir. 1985). Here, petitioners ignore their complete failure to meet that obligation. Accordingly, in light of the voluminous evidence of '195's nonenablement, it was appropriate for the court below to consider as one factor the complete absence of any relevant evidence supporting enablement. *See* Pet. App. at 32-34.

(Fed. Cir.), *cert. denied*, 481 U.S. 1052 (1987). The application of that Rule to the particular facts of this case is a completely fact-bound question and does not merit review by this Court of the 35,000 page factual record in this case.

In any event, the court of appeals correctly held that the district court "erred, as a matter of law, in concluding that the claims requiring 160,000 IU/AU by an *in vivo* measurement were enabled" on the basis of evidence of *in vitro* activity. Pet. App. 32. First, the court of appeals properly discounted reliance on Kung's *in vitro* test because of the district court's own findings that the claims of the '195 patent require *in vivo* not *in vitro* specific activity. *See id.* at 33, 164. Because the district court had used an *in vivo* measure to determine the definiteness of the '195 claims, as a matter of law, only an *in vivo* measure could be used to determine enablement. *See, e.g., Tandon Corp.* v. *ITC*, 831 F.2d 1017, 1021 (Fed. Cir. 1987); *Smithkline Diagnostics, Inc.* v. *Helena Laboratories Corp.*, 859 F.2d 878, 882 (Fed. Cir. 1988).

Second, the plain and simple fact is that petitioners *admitted to the FDA* that uEPO purified to homogeneity has *in vivo* specific activity of *only 109,000 IU/AU, i.e.*, an amount which is dramatically less than the 160,000 IU/AU required by the '195 patent claims. Pet. App. 32. The record contains no evidence to contradict that admission. *See id.* at 32-33, 173-75. Thus petitioners' own statement proved that '195's claims were not enabled. Furthermore, research by third parties confirmed that the *in vivo* specific activity claimed for uEPO using '195's techniques was never achieved. *See id.* at 33-34.

Third, with respect to rEPO, the undisputed pertinent evidence showed that GI affirmatively failed to achieve the level of *in vivo* specific acivity required by the claims of the '195 patent using the teachings provided by the supporting specification. Pet. App. 33-34. Three con-

trolling facts were found by the district court and relied on by the court of appeals but are completely ignored by petitioners: (1) "The purification procedure . . . reported in the '195 patent, did not result in purified rEPO, but rather the resulting solution . . . had only 62 percent EPO." *Id.* at 92. (8) "The patent does not contain any procedures for . . . purifying rEPO to the point that RP-HPLC will be successful." *Id.* (3) "It is undisputed that GI tried and failed to purify rEPO using RP-HPLC, and this failed experiment is disclosed in Example 2 of the patent." *Id.* at 186. Accordingly, as the court of appeals noted, the '195 patent specification is, itself, evidence of its own inadequacy, and thus "the '195 patent fails to enable purification of either rEPO or uEPO." *Id.* at 34.

CONCLUSION

The petition for a writ of certiorari should be denied.

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